

JC06 Rec'd PCT/PTC 23 SEP 2009

Docket No.: 3765-0114PUS1

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Marco Maria GENTILE et al.

Application No.: 10/531,579

Confirmation No.: 1844

Filed: April 18, 2005

Art Unit: 1621

For: NO PAIN INJECTABLE COMPOSITIONS

CONTAINING SALTS OF 2-ARYLPROPIONIC ACIDS Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

a. Copies of cited U.S. patents and patent application publications are not included.

Copies of foreign patent documents and non-patent literature are included.

Application No.: 10/531,579 Docket No.: 3765-0114PUS1

b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

a. <u>DOCUMENTS IN THE ENGLISH LANGUAGE</u> - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

b. <u>DOCUMENTS NOT IN THE ENGLISH LANGUAGE</u> - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:



Docket No.: 3765-0114PUS1

Application No.: 10/531,579

ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search c. report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3). OTHER - The following additional information is provided for the Examiner's d. consideration. FEES (check one box) IV. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required. This Information Disclosure Statement is being filed concurrent with the filing of b. a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required. This Information Disclosure Statement is being filed within three months of the c. filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's.) d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. $\S 1.97(b)(2)$). No fee or statement is required. This Information Disclosure Statement is being filed concurrently with the filing e. of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.



Docket No.: 3765-0114PUS1

Application No.: 10/531,579

f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check <u>only</u> one box)

The undersigned hereby states that:

a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or

b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

4 DRN/kj

Application No.: 10/531,579 Docket No.: 3765-0114PUS1

No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. <u>PAYMENT OF FEES</u> (check one box)

No fee is required.

X

Account No. 02-2448.

The required f	ee is listed	on the attache	d Fee T	ransmittal.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit

5 DRN/kj

Application No.: 10/531,579

Docket No.: 3765-0114PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: September 23, 2005

Respectfully submitted,

Mark J. Nuell, Ph.D.

Registration No.: 36,623

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Rd Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachment(s):

\boxtimes	PTO-SB08
\boxtimes	Documents
	Foreign Search Report
	Fee
\Box	Other:

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known		
				Application Number	10/531,579	
	NFORMATION	I DI	SCLOSURE	Filing Date	April 18, 2005	
1 :	STATEMENT I	3Y A	APPLICANT	First Named Inventor	Marco Maria GENTILE	
				Art Unit	1621	
į	(Use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned	
Shee	Sheet 1 of 1		Attorney Docket Number	3765-0114PUS1		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	

FOREIGN PATENT DOCUMENTS							
Evaminar	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,		
Examiner Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵	
	ВА	WO-97/24114-A1	07-10-1997			1	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	CA	G.A. BRAZEAU et al., Journal of Pharmaceutical Sciences, Vol. 87, No. 6, June 1998, pp. 667-677.				
	СВ	J. SCOTT et al., Pain, Vol. 2, 1976, pp. 175-184.				

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner		Date	
Signature		Considered	

¹Applicant's unique citation designation number (optional). 2Applicant is to place a check mark here if English language Translation is attached.